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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL		5092

7590 10/28/2002  
LORUSSO & LOUD  
440 COMMERCIAL STREET  
BOSTON, MA 02109

EXAMINER

MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/28/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

T.P

<b>Office Action Summary</b>	<b>Application No.</b> 08/932,227	<b>Applicant(s)</b> FOSSEL, ERIC T.	
	<b>Examiner</b> Jeffrey C. Mullis	<b>Art Unit</b> 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-44, 47-53, 56-59 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-44, 47-53, 56-59 and 61-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

All remaining rejections and/or objections follow.

The amendment filed 7-29-02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The last paragraph of the material added to the specification at line 2 on page 6 (i.e. the paragraph beginning "(A)s displayed in the Examples above an effective concentration". While these ranges are disclosed for specific compositions, they are not broadly disclosed.

Applicant is required to cancel the new matter in the response to this Office action.

Claims 33-35, 38-44, 47-53, 56-59 and 61-63 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not disclose L-arginene and L-arginine with concentrations broadly of 0.25-25% by weight or ionic salt concentrations of 0.25-25% by weight but at most only discloses such concentrations for specific compositions. Applicants' concentration ranges are therefore new matter.

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Applicants' arguments filed 7-29-02 have been fully considered but they are not deemed to be persuasive.

Applicants' remarks regarding the art rejections are moot since these rejections have been withdrawn upon reconsideration of applicants' Declaration and applicants' present remarks.

Applicants' remarks regarding the rejection under 35 U.S.C. § 112 second paragraph are moot since this rejection has also been withdrawn.

With regard to the rejection under 35 U.S.C. § 112 first paragraph whether or not the issue is sufficient support or new matter, it is the position of the Examiner that the claims are still properly rejected under 35 U.S.C. § 112 first paragraph. In re Rasmussen holds that a claim amended in such a way as to have no support in the original disclosure should be rejected under 35 USC 112 first paragraph as was done by the examiner. Applicants argue that applicants' ranges are supported by the specification at page 6 since the specification at page 6 discloses that various forms of L-arginine may be used and therefore one skilled in the art would be sufficiently taught by the specification to use this range for all forms. While it may be true that those skilled in the art might conclude that applicants' ranges were valid for all disclosed species and consider it obvious to use applicants' ranges for all species, it cannot be said that

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applicants' ranges are disclosed for all species. This issue does not appear to have any relevancy to inherency.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

JCM

10-25-02

Jeffrey M. Smith  
Primary Examiner  
Art Unit 1711

